AMENDMENT IN THE NATURE OF A SUBSTITUTE TO COMMITTEE PRINT (RELATING TO H.R. 1132) OFFERED BY MR. WHITFIELD OF KENTUCKY

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the ''National All Schedules Prescription Electronic Reporting Act of 2005''.

SEC. 2. PURPOSE.

It is the purpose of this Act to—

(1) foster the establishment of State-administered controlled substance monitoring systems in order to ensure that health care providers have access to the accurate, timely prescription history information that they may use as a tool for the early identification of patients at risk for addiction in order to initiate appropriate medical interventions and avert the tragic personal, family, and community consequences of untreated addiction; and

(2) establish, based on the experiences of existing State controlled substance monitoring programs, a set of best practices to guide the establishment of

new State programs and the improvement of existing programs.

SEC. 3. CONTROLLED SUBSTANCE MONITORING PROGRAM.

Part P of title III of the Public Health Service Act (42 U.S.C. 280g et seq.) is amended by adding after section 399N the following:

"SEC. 399O. CONTROLLED SUBSTANCE MONITORING PROGRAM.

''(a) GRANTS.—

''(1) IN GENERAL.—Each fiscal year, the Secretary shall award a grant to each State with an application approved under this section to enable the State—

''(A) to establish and implement a State controlled substance monitoring program; or

''(B) to make improvements to an existing State controlled substance monitoring program.

''(2) DETERMINATION OF AMOUNT.—

''(A) MINIMUM AMOUNT.—In making payments under a grant under paragraph (1) for a fiscal year, the Secretary shall allocate to each State with an application approved under this section an amount that equals 1.0 percent of the amount appropriated to carry out this section for that fiscal year.

"(B) ADDITIONAL AMOUNTS.—In making payments under a grant under paragraph (1) for a fiscal year, the Secretary shall allocate to each State with an application approved under this section an additional amount which bears the same ratio to the amount appropriated to carry out this section for that fiscal year and remaining after amounts are made available under subparagraph (A) as the number of pharmacies of the State bears to the number of pharmacies of all States with applications approved under this section (as determined by the Secretary), except that the Secretary may adjust the amount allocated to a State under this subparagraph after taking into consideration the budget cost estimate for the State's controlled substance monitoring program.

"(3) TERM OF GRANTS.—Grants awarded under this section shall be obligated in the year in which funds are allotted.

"(b) DEVELOPMENT OF MINIMUM REQUIREMENTS.—Prior to awarding a grant under this section, and not later than 6 months after the date on which funds are first appropriated to carry out this section, the Secretary shall, after publishing in the Federal Register pro-

posed minimum requirements and receiving public comments, establish minimum requirements for criteria to be used by States for purposes of clauses (ii), (v), (vi), and (vii) of subsection (c)(1)(A).

''(e) APPLICATION APPROVAL PROCESS.—

''(1) IN GENERAL.—To be eligible to receive a grant under this section, a State shall submit an application to the Secretary at such time, in such manner, and containing such assurances and information as the Secretary may reasonably require. Each such application shall include—

''(A) with respect to a State that intends to use funds under the grant as provided for in subsection (a)(1)(A)—

''(i) a budget cost estimate for the controlled substance monitoring program to be implemented under the grant;

''(ii) criteria for security for information handling and for the database maintained by the State under subsection (e) generally including efforts to use appropriate encryption technology or other appropriate technology to protect the security of such information;

''(iii) an agreement to adopt health information interoperability standards, including health vocabulary and messaging standards, that are consistent with any such standards generated or identified by the Secretary or his or her designee;

''(iv) criteria for meeting the uniform electronic format requirement of subsection (h);

''(v) criteria for availability of information and limitation on access to program personnel;

''(vi) criteria for access to the database, and procedures to ensure that information in the database is accurate;

''(vii) criteria for the use and disclosure of information, including a description of the certification process to be applied to requests for information under subsection (f);

''(viii) penalties for the unauthorized use and disclosure of information maintained in the State controlled substance monitoring program in violation of applicable State law or regulation;

"(ix) information on the relevant State laws, policies, and procedures, if any, regarding purging of information from the database; and

"(x) assurances of compliance with all other requirements of this section; or

"(B) with respect to a State that intends to use funds under the grant as provided for in subsection (a)(1)(B)—

"(i) a budget cost estimate for the controlled substance monitoring program to be improved under the grant;

"(ii) a plan for ensuring that the State controlled substance monitoring program is in compliance with the criteria and penalty requirements described in clauses (ii) through (viii) of subparagraph (A);

"(iii) a plan to enable the State controlled substance monitoring program to achieve interoperability with at least one other State controlled substance monitoring program; and

"(iv) assurances of compliance with all other requirements of this section or a statement describing why such compliance

is not feasible or is contrary to the best interests of public health in such State.

''(2) STATE LEGISLATION.—As part of an application under paragraph (1), the Secretary shall require a State to demonstrate that the State has enacted legislation or regulations to permit the implementation of the State controlled substance monitoring program and the imposition of appropriate penalties for the unauthorized use and disclosure of information maintained in such program.

''(3) INTEROPERABILITY.—If a State that submits an application under this subsection geographically borders another State that is operating a controlled substance monitoring program under subsection (a)(1) on the date of submission of such application, and such applicant State has not achieved interoperability for purposes of information sharing between its monitoring program and the monitoring program of such border State, such applicant State shall, as part of the plan under paragraph (1)(B)(iii), describe the manner in which the applicant State will achieve interoperability between the monitoring programs of such States.

''(4) APPROVAL.—If a State submits an application in accordance with this subsection, the Secretary shall approve such application.

''(5) RETURN OF FUNDS.—If the Secretary withdraws approval of a State's application under this section, or the State chooses to cease to implement or improve a controlled substance monitoring program under this section, a funding agreement for the receipt of a grant under this section is that the State will return to the Secretary an amount which bears the same ratio to the overall grant as the remaining time period for expending the grant funds bears to the overall time period for expending the grant (as specified by the Secretary at the time of the grant).

''(d) REPORTING REQUIREMENTS.—In implementing or improving a controlled substance monitoring program under this section, a State shall comply, or with respect to a State that applies for a grant under subsection (a)(1)(B) submit to the Secretary for approval a statement of why such compliance is not feasible or is contrary to the best interests of public health in such State, with the following:

''(1) The State shall require dispensers to report to such State each dispensing in the State of

a controlled substance to an ultimate user not later than 1 week after the date of such dispensing.

''(2) The State may exclude from the reporting requirement of this subsection—

''(A) the direct administration of a controlled substance to the body of an ultimate user;

''(B) the dispensing of a controlled substance in a quantity limited to an amount adequate to treat the ultimate user involved for 48 hours or less; or

''(C) the administration or dispensing of a controlled substance in accordance with any other exclusion identified by the Secretary for purposes of this paragraph.

''(3) The information to be reported under this subsection with respect to the dispensing of a controlled substance shall include the following:

''(A) Drug Enforcement Administration Registration Number (or other identifying number used in lieu of such Registration Number) of the dispenser.

''(B) Drug Enforcement Administration Registration Number (or other identifying number used in lieu of such Registration Number)

and name of the practitioner who prescribed the drug.

''(C) Name, address, and telephone number of the ultimate user or such contact information of the ultimate user as the Secretary determines appropriate.

''(D) Identification of the drug by a national drug code number.

''(E) Quantity dispensed.

''(F) Number of refills ordered.

''(G) Whether the drug was dispensed as a refill of a prescription or as a first-time request.

''(H) Date of the dispensing.

''(I) Date of origin of the prescription.

''(J) Such other information as may be required by State law to be reported under this subsection.

''(4) The State shall require dispensers to report information under this section in accordance with the electronic format specified by the Secretary under subsection (h), except that the State may waive the requirement of such format with respect to an individual dispenser that is unable to submit such information by electronic means.

''(e) DATABASE.—In implementing or improving a controlled substance monitoring program under this section, a State shall comply with the following:

''(1) The State shall establish and maintain an electronic database containing the information reported to the State under subsection (d).

''(2) The database must be searchable by any field or combination of fields.

''(3) The State shall include reported information in the database in a manner consistent with criteria established by the Secretary, with appropriate safeguards for ensuring the accuracy and completeness of the database.

''(4) The State shall take appropriate security measures to protect the integrity of, and access to, the database.

''(f) USE AND DISCLOSURE OF INFORMATION.—

''(1) IN GENERAL.—Subject to subsection (g), in implementing or improving a controlled substance monitoring program under this section, a State may disclose information from the database established under subsection (e) and, in the case of a request under subparagraph (D), summary statistics of such information, only in response to a request by—

"(A) a practitioner (or the agent thereof) who certifies, under the procedures determined by the State, that the requested information is for the purpose of providing medical or pharmaceutical treatment or evaluating the need for such treatment to a bona fide current patient;

"(B) any local, State, or Federal law enforcement, narcotics control, licensure, disciplinary, or program authority, who certifies, under the procedures determined by the State, that the requested information is related to an individual investigation or proceeding involving the unlawful diversion or misuse of a schedule II, III, or IV substance, and such information will further the purpose of the investigation or assist in the proceeding;

"(C) the controlled substance monitoring program of another State or group of States with whom the State has established an interoperability agreement;

"(D) any agent of the Department of Health and Human Services, a State medicaid program, a State health department, or the Drug Enforcement Administration who certifies that the requested information is necessary for

research to be conducted by such department, program, or administration, respectively, and the intended purpose of the research is related to a function committed to such department, program, or administration by law that is not investigative in nature; or

''(E) an agent of the State agency or entity of another State that is responsible for the establishment and maintenance of that State's controlled substance monitoring program, who certifies that—

''(i) the State has an application approved under this section; and

''(ii) the requested information is for the purpose of implementing the State's controlled substance monitoring program under this section.

''(2) DRUG DIVERSION.—In consultation with practitioners, dispensers, and other relevant and interested stakeholders, a State receiving a grant under subsection (a)—

''(A) shall establish a program to notify practitioners and dispensers of information that will help identify and prevent the unlawful diversion or misuse of controlled substances; and

''(B) may, to the extent permitted under State law, notify the appropriate authorities responsible for carrying out drug diversion investigations if the State determines that information in the database maintained by the State under subsection (e) indicates an unlawful diversion or abuse of a controlled substance.

''(g) LIMITATIONS.—In implementing or improving a controlled substance monitoring program under this section, a State—

''(1) shall limit the information provided pursuant to a valid request under subsection (f)(1) to the minimum necessary to accomplish the intended purpose of the request; and

''(2) shall limit information provided in response to a request under subsection (f)(1)(D) to nonidentifiable information.

''(h) ELECTRONIC FORMAT.—The Secretary shall specify a uniform electronic format for the reporting, sharing, and disclosure of information under this section.

''(i) RULES OF CONSTRUCTION.—

''(1) FUNCTIONS OTHERWISE AUTHORIZED BY LAW.—Nothing in this section shall be construed to restrict the ability of any authority, including any local, State, or Federal law enforcement, narcotics

control, licensure, disciplinary, or program authority, to perform functions otherwise authorized by law.

''(2) NO PREEMPTION.—Nothing in this section shall be construed as preempting any State law, except that no such law may relieve any person of a requirement otherwise applicable under this Act.

''(3) ADDITIONAL PRIVACY PROTECTIONS.—Nothing in this section shall be construed as preempting any State from imposing any additional privacy protections.

''(4) FEDERAL PRIVACY REQUIREMENTS.—Nothing in this section shall be construed to supersede any Federal privacy or confidentiality requirement, including the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191; 110 Stat. 2033) and section 543 of the Public Health Service Act.

''(5) NO FEDERAL PRIVATE CAUSE OF ACTION.—Nothing in this section shall be construed to create a Federal private cause of action.

''(j) STUDIES AND REPORTS.—

''(1) IMPLEMENTATION REPORT.—

''(A) IN GENERAL.—Not later than 180 days after the date of enactment of this section,

the Secretary, based on a review of existing State controlled substance monitoring programs and other relevant information, shall determine whether the implementation of such programs has had a substantial negative impact on—

"(i) patient access to treatment, including therapy for pain or controlled substance abuse;

"(ii) pediatric patient access to treatment; or

"(iii) patient enrollment in research or clinical trials in which, following the protocol that has been approved by the relevant institutional review board for the research or clinical trial, the patient has obtained a controlled substance from either the scientific investigator conducting such research or clinical trial or the agent thereof.

"(B) ADDITIONAL CATEGORIES OF EXCLUSION.—If the Secretary determines under subparagraph (A) that a substantial negative impact has been demonstrated with regard to one or more of the categories of patients described in such subparagraph, the Secretary shall iden-

tify additional appropriate categories of exclusion from reporting as authorized under subsection (d)(2)(C).

''(2) PROGRESS REPORT.—Not later than 3 years after the date on which funds are first appropriated under this section, the Secretary shall—

''(A) complete a study that—

''(i) determines the progress of States in establishing and implementing controlled substance monitoring programs under this section;

''(ii) provides an analysis of the extent to which the operation of controlled substance monitoring programs have reduced inappropriate use, abuse, or diversion of controlled substances or affected patient access to appropriate pain care in States operating such programs;

''(iii) determines the progress of States in achieving interoperability between controlled substance monitoring programs, including an assessment of technical and legal barriers to such activities and recommendations for addressing these barriers;

''(iv) determines the feasibility of implementing a real-time electronic controlled substance monitoring program, including the costs associated with establishing such a program;

''(v) provides an analysis of the privacy protections in place for the information reported to the controlled substance monitoring program in each State receiving a grant for the establishment or operation of such program, and any recommendations for additional requirements for protection of this information;

''(vi) determines the feasibility of implementing technological alternatives to centralized data storage, such as peer-to-peer file sharing or data pointer systems, in controlled substance monitoring programs and the potential for such alternatives to enhance the privacy and security of individually identifiable data; and

''(vii) evaluates the penalties that States have enacted for the unauthorized use and disclosure of information maintained in the controlled substance moni-

toring program, and reports on the criteria used by the Secretary to determine whether such penalties qualify as appropriate pursuant to this section; and

''(B) submit a report to the Congress on the results of the study.

''(k) PREFERENCE.—Beginning 3 years after the date on which funds are first appropriated to carry out this section, the Secretary, in awarding any competitive grant that is related to drug abuse (as determined by the Secretary) and for which only States are eligible to apply, shall give preference to any State with an application approved under this section. The Secretary shall have the discretion to apply such preference to States with existing controlled substance monitoring programs that meet minimum requirements under this section or to States that put forth a good faith effort to meet those requirements (as determined by the Secretary).

''(l) ADVISORY COUNCIL.—

''(1) ESTABLISHMENT.—A State may establish an advisory council to assist in the establishment, implementation, or improvement of a controlled substance monitoring program under this section.

''(2) LIMITATION.—A State may not use amounts received under a grant under this section

for the operations of an advisory council established under paragraph (1).

''(3) SENSE OF CONGRESS.—It is the sense of the Congress that, in establishing an advisory council under this subsection, a State should consult with appropriate professional boards and other interested parties.

''(m) DEFINITIONS.—For purposes of this section:

''(1) The term 'bona fide patient' means an individual who is a patient of the practitioner involved.

''(2) The term 'controlled substance' means a drug that is included in schedule II, III, or IV of section 202(c) of the Controlled Substance Act.

''(3) The term 'dispense' means to deliver a controlled substance to an ultimate user by, or pursuant to the lawful order of, a practitioner, irrespective of whether the dispenser uses the Internet or other means to effect such delivery.

''(4) The term 'dispenser' means a physician, pharmacist, or other person that dispenses a controlled substance to an ultimate user.

''(5) The term 'interoperability' with respect to a State controlled substance monitoring program means the ability of the program to electronically share reported information, including each of the re-

quired report components described in subsection (d), with another State if the information concerns either the dispensing of a controlled substance to an ultimate user who resides in such other State, or the dispensing of a controlled substance prescribed by a practitioner whose principal place of business is located in such other State.

''(6) The term 'nonidentifiable information' means information that does not identify a practitioner, dispenser, or an ultimate user and with respect to which there is no reasonable basis to believe that the information can be used to identify a practitioner, dispenser, or an ultimate user.

''(7) The term 'practitioner' means a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he or she practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

''(8) The term 'State' means each of the 50 States and the District of Columbia.

"(9) The term 'ultimate user' means a person who has obtained from a dispenser, and who possesses, a controlled substance for his or her own use, for the use of a member of his or her household, or for the use of an animal owned by him or her or by a member of his or her household.

"(n) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated—

"(1) $15,000,000 for each of fiscal years 2006 and 2007; and

"(2) $10,000,000 for each of fiscal years 2008, 2009, and 2010.".